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Documents Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
HFA-305, Room 1061
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 00D-0053
FDA Draft Guidance on *Reprocessing and Reuse of Single Use Devices: Review Prioritization Scheme;* and FDA Draft Guidance on *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.*

Dear Sir or Madame:

This letter presents ECRI's written comments on FDA's two recently published documents entitled: FDA Draft Guidance on *Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme;* and FDA Draft Guidance on *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*. We present here comments on three specific areas of the proposed strategies:

1. The need to regulate all healthcare facilities – not just acute care hospitals

2. FDA's regulation of healthcare providers as original equipment manufacturers (OEMs) or third-party reprocessors.

3. Difficulties in developing risk categories and applying regulations to different types and classes of devices.

While ECRI acknowledges that some degree of oversight is warranted to ensure that reuse practices do not pose unacceptable risks to patients, FDA's proposed plan places onerous administrative and financial restrictions on hospitals that reuse SUDs. In addition, the proposed strategy will give FDA direct authority over hospital activities, as well as the right to impose regulatory sanctions. ECRI believes that the proposed scheme, in its current state, will result in one or more of the following:

1. All reuse will shift to third-party reprocessors, driving healthcare costs up.

2. Reuse will be driven further underground, thereby discouraging the open exchange of information and experience regarding reuse.

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3. Reuse will stop altogether, and the purchase of more expensive single-use devices will escalate, significantly driving up the cost of healthcare.

4. With reuse eliminated as a potentially viable alternative, manufacturers can and will raise prices. Keep in mind that typical hospitals spend eight to ten times more money on reusable equipment than on capital equipment each year.

Background

ECRI has a long-standing interest and marked expertise in the reuse of single-use medical devices. As an independent, non-profit health services research organization, ECRI has maintained a mission to protect the public from unsafe, ineffective, and costly medical technologies and related practices. In our thirty-year history, we have investigated tens of thousands of medical device related accidents, injuries, and deaths and have provided in-depth technical and intellectual resources for medical technology decision-makers.

Reuse of single-use medical devices is but one topic on which healthcare organizations have sought ECRI guidance. In our 1997 Special Report on reuse, *Single Use Devices: Making Informed Decisions* (copy available upon request), ECRI concluded that there is no clear evidence that reuse of single-use medical devices is either safe or unsafe for patients. We believe that conclusion holds true today. ECRI also concluded that safe, effective, and properly documented reprocessing of a single-use device may be a daunting task for certain users (e.g. hospitals, surgicenters, clinics, physicans' offices, nursing homes, etc.) We have provided FDA with several copies of ECRI's Special Report, and understand that FDA, hospitals and industry have relied upon this study for guidance on reuse of single-use devices. ECRI has also been an active participant in several FDA public meetings on reuse.

The reuse of SUDs undeniably carries with it a number of *potential* risks related to infection, sterilization, materials degradation and compromised device performance. Device performance is also a problem with new and never reprocessed devices. Recent debates on reuse have pointed to anecdotal examples of a few incidents involving a limited number of device types and an even more limited number of specific makes and models of SUDs. At the AAMI/FDA conference on the reuse of single-use devices in May 1999, Mark Bruley, ECRI's Vice President of Accident and Forensic Investigation, presented ECRI's analysis of the FDA databases and the medical literature related to reported problems with reuse and published studies of reuse safety and efficacy. Despite approximately twenty years of reuse of SUDs, there is a dearth of evidence of actual incidents of patient injuries or deaths. This contrasts starkly against the backdrop of tens of thousands of deaths annually from medical errors that have received much recent attention and suggests a rethinking of regulatory priorities and the application of limited FDA resources.

ENFORCEMENT PRIORITIES

The Need to Regulate All Healthcare Facilities - Not Just Acute Care Hospitals

Reuse of single-use devices is an activity conducted by the providers of healthcare as a subset of their business activities directed at caring for the ill. To obtain jurisdiction over the reuse of single -use devices, FDA has classified hospitals as "manufacturers" of reusable devices rather than as providers of "medical services." FDA has adopted this verbiage, when referring to the practice of reuse of SUDs, because, until now, it has been precluded from regulating the "practice of medicine." ECRI believes that FDA's characterization of reuse at hospitals as "manufacturing" is fundamentally incorrect. In addition, hospitals and healthcare facilities are not engaged in any form of interstate commerce and their services do not cross state lines. As such, they generally do not fall within the scope of FDA's regulatory control. Therefore, ECRI is requesting that FDA articulate the basis for its jurisdiction over hospitals with respect to the reuse of single-use devices. In addition, we are requesting that the Agency clarify its definition of "manufacturer" under the Food, Drug & Cosmetic Act as it relates to this issue.

FDA's characterization of hospitals as "manufacturers" also generates liability concerns for those hospitals that reprocess SUDs. Specifically, who will bear liability if a patient injury results from reuse of a single-use device? Under current judicial opinions hospitals are usually characterized as providers of services rather than as vendors of goods. As such, they may invoke a product liability defense related to the utilization of a defective device. FDA's proposed plan to regulate hospitals as manufacturers of SUDs may bar hospitals from claiming such a defense and ultimately expose facilities to single-use device claims of strict liability, breach of warranty, or negligence. Hospitals could also be liable for failing to dispose of an SUD with compromised functional integrity.

Further, the application of FDA's jurisdiction, with respect to the reuse of SUDs, is discriminate and applied unequally within the healthcare industry. ECRI believes that the decision to regulate reuse by hospitals is just as much an intrusion into the practice of medicine by a healthcare facility as would be a proposal to apply these regulations to a private physician's office. However, the regulation of the physician office practice is an issue that the debate on reuse has, so far, delicately skirted. The FDA and Congress have always maintained that they do not claim an authority to interfere with a physician's practice of medicine in his or her provision of patient care. Witness the exemption of physician practices from the requirements of FDA's MedWatch medical device reporting regulations.

However, the complexion of medicine is rapidly changing, and today, many physicians' offices offer a wide range of procedures and services that rival the care given at surgicenters and hospital outpatient clinics. For example, in vitro fertilization, cytoscopy, and some plastic surgeries are now commonly performed in private physicians' offices, with the same complement of single-use instruments and devices used in the hospital or surgicenter and with the same potential risks of infection or device failure from reprocessing of those single-use products.

If the reuse of SUDs is a hazard with risks sufficient to warrant FDA regulation of healthcare facilities, then the same logic must apply to physician offices, group practices and to ambulatory surgical centers. To exempt non-hospital facilities, at this time, runs counter to FDA's efforts to ensure and to enhance patient safety associated with the reuse of SUDs. Further, private physician offices, ambulatory surgical centers and group practices often lack the resources and protocols that an acute care facility would have in place to provide for safe and effective reprocessing of single-use items. As such, regulation of the physician practice or of the free-standing surgical center that reuses single-use devices must be considered equally with the regulation of a healthcare facility that engages in this practice.

In addition, FDA's failure to establish a level playing field with respect to the reuse of SUDs will ultimately place hospitals at a competitive disadvantage with other types of healthcare providers. Some medical forecasters are projecting that physician offices and ambulatory surgical centers will become the dominant settings for surgeries by the year 2005. Therefore, in

the interest of patient safety, it is incumbent upon FDA to regulate reuse outside of the traditional acute care setting. The application of these regulations must apply to all facets of the proposed regulations: enforcement timing, audits/inspections, mandatory FDA registration, and data submission.

In lieu of direct FDA regulation of healthcare facilities and physician offices, it has been recognized by FDA, in item No. One (1) of its proposed strategy, that the Agency would consider "collaborating with accredited third-party organizations. . . to ensure that the reprocessing operations are being performed in accordance with the Agency's requirements." ECRI would suggest that FDA collaborate with third-party organizations such as the American Hospital Association and/or the Joint Commission on Accreditation of Healthcare Organizations.

Regulation of Healthcare Providers as OEMs and Third-Party Reprocessors

Although some degree of regulation or accreditation oversight is warranted to help ensure that the current level of reuse, or that a future increase in reuse, does not pose unacceptable risks to patients, ECRI disagrees with the proposed FDA approach to regulate healthcare organizations in the same manner as OEMs and third party reprocessors. To impose the same regulatory requirements on healthcare organizations is inappropriate and unreasonable. FDA recognizes that its proposed regulations will impose upon healthcare providers an additional regulatory burden with which they are ill-equipped to comply. FDA also recognizes that hospitals must already answer to state licensing boards, the Health Care Financing Administration, and a variety of other regulatory bodies. Further, this additional layer of FDA regulatory oversight, if truly to be considered for application to healthcare providers, must be seriously weighed against the potential benefit to the public, the costs of FDA implementation, and any evidence of significant risk to patients from reuse.

Should FDA proceed with enforcing all premarket requirements on hospitals that reprocess, it is highly probable that hospitals will elect to discontinue internal reprocessing activities and either turn to third party reprocessing companies or cease reprocessing SUDs altogether. Further, the

investment of resources necessary for hospitals to comply with Good Manufacturing Practices (GMPs), as well as premarket and 510K and application requirements would eliminate any cost savings hospitals would realize by reprocessing single-use devices. ECRI believes that this would only serve to increase the costs of care in hospitals without significantly adding benefit to the current reprocessing activities in which hospitals engage.

In addition, the regulation of reuse by FDA places enormous administrative and financial burdens upon the Agency. In effect, it triples the number of manufacturers that FDA must regulate. FDA readily admits that its current resources would not permit enforcement of all regulatory requirements. Moreover, the Agency stipulates that hospitals may be unfamiliar with FDA regulations and will need time to learn about the regulations and to develop programs to comply with these requirements. To combat these obstacles, the Agency has established a "phase-in" approach for the enforcement of regulatory requirements for third-party and hospital reprocessors. However, the Agency has made no mention of what, if any, guidance or education it intends to offer to the approximately 4,000 to 5,000 hospitals that reuse SUDs.

These difficulties are further compounded by some noted inconsistencies in the Agency's proposed regulations. For example, In Section D of the Document (page four), the Agency states that, "With respect to premarket requirements, FDA intends to begin to enforce premarket notification and premarket application requirements within six (6) months of issuance of a final guidance if the reprocessed device is categorized as high risk." Later in Section F of this same document (page fifteen), FDA states that it "intends to continue to exercise its discretion to not enforce premarket requirements for third party and hospital reprocessors of devices that are considered high risk for one (1) year from the date of issuance of a final SUD enforcement guidance provided:"

1. FDA receives a 510K submission of a PMA application within six (6) months of the issuance of the final enforcement SUD enforcement guidance;

2. The 510K submission or PMA application is complete and is of sufficient quality to be acceptable for substantive review; and

3. The applicant receives an FDA order finding the device substantially equivalent and cleared for marketing, or an order approving a premarket approval application within six (6) months of the filing date.

ECRI believes that these statements are contradictory and circuitous in logic. As a result, hospitals that reprocess will likely find the requirements for premarket submission confusing and cumbersome. Therefore, ECRI is requesting that FDA clarify its proposed guidance with respect to premarket requirements. (Please note that these same discrepancies exist within the document for moderate and low risk devices).

In yet another instance, ECRI takes issue with FDA's proposed guidance on Registration and Listing (page six). The Agency states that "The initial list of all SUDs that an establishment reprocesses must be reported on Form FD-2892 ("Medical Device Listing"). These instructions

require clarification. Specifically, FDA has failed to indicate whether the SUD must be reported at the model number level detail or to the serial number/lot number detail. For the sake of accuracy and expediency, FDA must clearly "spell out" all requirements in one guidance document. The current instructions are cumbersome and will force hospitals to search through multiple documents for guidance on medical device listing.

COMMENTS ON FDA'S REVIEW PRIORITIZATION SCHEME

Difficulties in Developing Risk Categories

As previously stated in ECRI's December 22, 1999, comments to FDA, ECRI believes that the proposed Review Prioritization Scheme (RPS), in its current form, is a cumbersome and ineffective vehicle for classifying and regulating SUDs either by risk category or by general device type. Due to the specific design dimensions and materials used in disposable medical devices, the Review Prioritization Scheme can, at best, provide "three-tiered" regulatory guidance on classifying SUDs based upon their risk of infection and/or their inadequate performance after reprocessing. Further, those medical device definitions, contained within the regulation numbers of Appendix 2 of the Review Prioritization Scheme, and in the identical Appendix B of the Enforcement Priorities, were drafted prior to the introduction of most of these disposable medical devices to the market. The use of these regulatory device definitions is, therefore, of only marginal value in assessing the risk category for each of the devices identified as frequently reprocessed SUDs.

Further, the limitations of FDA's current approach are acutely evident in the classification of a number of devices cited in Appendix 2. For example, some of device categories such as "arthroscopy instruments" or "endoscopes" or "laparascopes" are so expansive and so vague that they offer little if any guidance when assessing the risk category of an exact device. Specifically, under the category "respiratory devices," FDA has cited "oral and nasal catheters" as low risk devices. These devices routinely come in contact with mucosal surfaces, and depending upon their size, shape and durometer can be difficult if not impossible to clean. Further, these oral and nasal catheters are more akin to the "respiratory therapy and anesthesia breathing circuits" that are categorized as "moderate" in risk.

Similarly, ECRI takes issue with FDA's disparate treatment of operating room drapes and surgical gowns: drapes are rated as a moderate risk whereas surgical gowns are rated as low risk. ECRI believes that there are no subjective differences distinguishing the two with respect to risk of infection or device performance. Of those disposable styles available, both gowns and drapes may be made of identical non-woven disposable textile materials and their roles are identical in preventing bacterial strike-through. Assigning them to different risk categories is incorrect. In this regard, please note that example two (page thirteen) of FDA's RPS guidance document is specifically targeted toward evaluating the risk from operating room drapes. ECRI also disagrees with FDA's assessment related to question three (3) of the example: " Does the operating room drape have any feature that could impede thorough cleaning and adequate sterilization?" The example proffered by FDA concludes that the answer to this question is "no" and consequently places operating room drapes in a "low risk" classification for infection. In reality, the surgical

nonwoven disposable textiles for drapes are not capable of withstanding the mechanical stresses of laundering. As such, the answer to this question is "yes" and the risk categorization for infection control should be "moderate."

In yet another instance, ECRI takes issue with FDA's classification of several categories of trocars as "moderate" in risk. Clearly, these devices warrant the classification of "high risk." Further muddying the waters is the fact that the vast majority of disposable surgical trocars currently available are of a design which is not clearly reflected in the definitions contained within FDA's regulations. Rather, modern disposable trocars are critical devices that, unlike their reuseable counterparts, cannot be opened for removal of debris; the same is true for their associated cannulae and attached insufflation/desufflation valve bodies. As a result, blood and soil may remain within the trocar's shield and commingle with a subsequent patient's blood or other body fluids when the trocar enters the abdominal cavity, thorax, or bladder. Such commingling and the potential for infection also exists with the associated cannulae. Further compounding the risk to the patient is the fact that many disposable trocars are manufactured with lubricants within the complicated mechanisms of the protective shields for the sharp trocar point. Cleaning and resterilization, regardless of the method or technique, is likely to degrade this lubrication and may compromise the disposable trocar's functional performance of the protective shield. At present, ECRI can envision no disposable trocars that would receive anything other than a "high risk" rating with respect to the risks from reprocessing after reuse. More to the point, ECRI recommends against the reprocessing of any used disposable trocar.

To prevent the misclassification of SUDs and the anticipated confusion it will create for hospitals, ECRI recommends that FDA make its entire Review Prioritization Scheme a transparent and a public one. Specifically, ECRI is asking that all device-specific questions and answers placed in the RPS flowcharts, as well as any and all supporting documentation used to establish the risk categorization for a specific type of device(s), be published and made available for public review. Further, ECRI strongly believes that FDA should work with a panel of multi-disciplinary professionals, such as those employed at ECRI, to establish and refine an accurate final categorization for each device. Only then can FDA create an evidence-base that is sufficient to validly reprocess SUDs safely and accurately.

ECRI also takes issue with the "rigid" parameters of the current proposed guidance which allow for little, if any, modifications of risk categorizations and enforcement priorities. ECRI believes that as new devices and new information about older devices develop, so too must the regulation of reuse evolve. Therefore, ECRI recommends that FDA incorporate a fluid "appeals process" into its reuse regulations, whereby FDA can re-classify devices, reassess risk categories, add devices and change or alter definitions as new data is presented. This appeals process should provide definitive timelines for reviewing postmarket data, as well as for adding, evaluating, and changing existing device categories.

As further support for the adoption of an "appeals process," ECRI notes FDA's proposed plan to classify all devices not already on the list of commonly reused SUDs, as "high risk". This sweeping categorization of a potentially unrelated grouping of devices as "high risk" will likely create unnecessary and burdensome standards for reprocessors and for FDA. Conversely, the

creation of an "appeals process" will allow for the timely submission of device-specific data, a more accurate assessment of each device, and the accurate assignment of a commensurate level of risk. ECRI believes that it is the level of regulation, and not the timing of the enforcement, that should correlate with the level of risk posed by the reprocessing of a single-use device.

Please contact me at ECRI at (610) 825-6000, ext. 5140, with questions on our comments or for a complementary copy of our reuse monograph.

Sincerely,

Joel J. Nobel, M.D.
President
ECRI